



VIA ELECTRONIC DELIVERY

September 17, 2010

The Honorable Kathleen Sebelius Secretary U.S. Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, D.C. 20201

RE: Comments on OCIIO-9992-IFC, Interim Final Rules for Group Health Plans and Health Insurers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act

Dear Madam Secretary:

The National Health Law Program (NHeLP) is a national public interest law firm that seeks to improve health care for America's working and unemployed poor, people of color, the elderly, women, children, and people with disabilities. We are pleased to submit these comments on the Interim Final Rules for Group Health Plans and Health Insurers Relating to Coverage of Preventive Services under the Patient Protection and Affordable Care Act (PPACA). Because numerous studies have documented the negative impact that cost-sharing requirements have on the utilization of health care for low-income populations, NHeLP strongly supports the requirements that insurers cover preventive services without cost-sharing mandates.¹

Moreover, we also offer the following recommendations to strengthen the Interim Final Rules:

- 1) Expand preventive services to include comprehensive contraception, prenatal counseling and well-woman health visits;
- 2) Eliminate the delay in extending preventive services for women's health;
- 3) Extend Section 2713 as enacted in PPACA to Medicaid managed care programs, including EPSDT services for youth;
- 4) Incorporate the necessary nondiscrimination requirements of PPACA §1557 into these regulations; and
- 5) Require preventive services to be delivered in a culturally sensitive and linguistically appropriate manner.

1 See e.g., J. Newhouse, Free for All? Lessons from the RAND Health Insurance Experiment, RAND (1996).

OTHER OFFICES

Preventive Services for Women's Health Should be Comprehensive and Include Comprehensive Contraception, Prenatal Counseling and Well-Woman Visits

PPACA sec. 1001, adding new sec. 2713 to the Public Health Services Act, requires a specific focus on preventive health services for women, with guidelines for such services by the Health Resources and Services Administration (HRSA). Although the recommended services provided in the Interim Final Rules place a strong emphasis on women's health, failing to include contraception, well-woman visits and prenatal counseling provides women with limited and incomplete preventive health care and further perpetuates disparities in health care services.

Contraception use prevents unintended pregnancy, which will help improve maternal health and mitigate disparities in health care

Supporting women in their ability to prevent unintended pregnancies has been a federal initiative since 1979, when it was first reported as one of five top priorities in *Healthy People*.² Since then, family planning has remained a top focus area³. In 2006, nearly half of all American women were at risk of an unintended pregnancy: that is, 36.2 million women between the ages of 13-44, sexually active with a male and capable of becoming pregnant, and neither pregnant nor seeking to become pregnant.⁴ In addition, in 2001, 49 percent of pregnancies were unintended, meaning they were either unwanted or mistimed.⁵

Having insurance does not guarantee coverage to contraception. Currently, only 27 states require insurers cover contraceptive services. However, of those 27 states, 19 allow certain employers and insurers to not comply with state mandates to offer coverage for contraception. Paying for contraception out-of-pocket is an expense that can sometimes be more than the cost of other medications. Depending on a woman's economic circumstances, paying for contraceptive services and devices simply may not be feasible. Women who lack full coverage of contraception may forgo obtaining contraception, and, as a result, be at higher risk of having an unintended or unwanted pregnancy. Moreover, it is important for Preventive Services to cover all FDA-approved contraceptive drugs, devices, and supplies including over-the-counter contraceptives to ensure that women can choose a contraceptive method that is best suited to their needs and health status.

The importance of women's ability to prevent pregnancy is well established within medical guidelines across a range of practice areas for many reasons. First, there are many numerous negative health effects of unwanted pregnancy. Unwanted pregnancy is associated with maternal morbidity and risky health behaviors, as well as low-birth weight babies and insufficient prenatal care. The American College of Obstetricians and Gynecologists (ACOG) notes that women who become pregnant less than six months after their previous pregnancy are 70 percent more likely to have membranes rupture permanently and are

² A. Sonfield, *Contraception: An Integral Component of Preventive Care for Women*, 13 POLICY REVIEW 2 (2010), (Guttmacher Inst., Washington, D.C.), *available at* http://www.guttmacher.org/pubs/gpr/13/2/gpr130202.pdf (last visited Sept. 15, 2010).

³ Family planning has continued to be a subject of *Healthy People*; it was featured as Goal 9 in *Healthy People* 2010.

⁴ Guttmacher Inst., *Contraceptive Needs and Services*, 2006 (2009), http://www.guttmacher.org/pubs/win/allstates2006.pdf (last visited Sept. 17, 2010).

⁵ L.B. Finer & S.K. Henshaw, *Disparities in rates of unintended pregnancy in the United States, 1994 and 2001*, 38 PERSPECTIVES ON SEXUAL & REPRODUCTIVE HEALTH 90 (2006), *available at* http://www.guttmacher.org/pubs/psrh/full/3809006.pdf.

⁶ Nat'l Family Planning & Reproductive Health Ass'n, *Family Planning: An Essential, Cost Effective Part of Health Care Reform*, http://www.nfprha.org/images/pdf/TransitionPaper.pdf (last visited September 15, 2010).

⁷ *Id*

⁸ S.S. Brown & L. Eisenberg, *Institute of Medicine Committee on Unintended Pregnancy: The best intentions: unintended pregnancy and the well-being of children and families*, National Academy Press (1995).

at significantly higher risk of other complications. In addition, the World Health Organization recommends that women space their pregnancies at least two years apart so that their bodies can recover from the pregnancy. If a woman becomes pregnant while breastfeeding, the health of her baby and the fetus can be compromised as she shares nutrients between them. ¹⁰

Second, for women with chronic diseases, such as diabetes, epilepsy, depression, lupus or some forms of cardiovascular disease, pregnancy may worsen the woman's condition. In addition, drug course treatments for these diseases may cause severe fetal impairments.¹¹ For these women, failure to obtain contraceptive services may result in adverse medical consequences, both to the woman and the fetus.

Last, children born from wanted pregnancies tend to be healthier than those born from unwanted pregnancies.¹² Women with unintended pregnancies are less likely to seek adequate prenatal care, if at all, and thus risk a greater chance of complications during pregnancy and birth. Without adequate prenatal care, there is greater risk of unchecked fetal abnormalities and decline in fetal health.¹³

Poor women and women of color are also more likely to have unintended pregnancies, and therefore, more likely to suffer health consequences from unintended pregnancies. According to *Healthy People* 2010, poor women and African-American women are more likely to have unintended pregnancies, with 7 out of 10 pregnancies being unintended, and a study by the CDC reports that "pregnancy rates for female Hispanics aged 15-19 years are much higher (132.8 and 128.0 per 1,000 population) than their non-Hispanic white peers (45.2 per 1,000 population). Marginalized groups also often lack access to obtain or pay for adequate health care. As explained in *Healthy People 2010*, although Medicaid provides family planning services, "reimbursement for family planning services is typically not available to adolescents, women without children, women who are married, and working poor women whose income may just exceed the eligibility level." 16

Adolescents are also at high risk of unintended pregnancy, and access to contraception should be made available to teens that are sexually active. In 2004, teen pregnancies accounted for roughly eleven percent of all pregnancies, and 2006 data shows a three percent rise in birth rates among 15- to 19-year-old women. ¹⁷ In addition, the proportion of unintended pregnancies is highest among women under 20 years old; while about 50 percent of pregnancies among adult women are unintended, 85 percent of pregnancies among teens are unintended. ¹⁸ The use of contraception during initial sexual activity is also strongly

⁹ Am. Coll. of Obstetricians & Gynecologists, State of the American College of Obstetricians and Gynecologists: Safe Motherhood (2002).

¹⁰ C. Marston, *Report of a WHO Technical Consultation on Birth Spacing*, (WHO, Geneva, Switz.), Jun. 13-15, 2005, *available at* http://whqlibdoc.who.int/hq/2007/WHO_RHR_07.1_eng.pdf (last visited Sept. 17, 2010).

¹¹ The CDC reports that three percent of women who could potentially become pregnant are taking teratogens. CDC, Recommendations to improve preconception health and health care – United States: a report of the CDC/ATSDR Preconception Care Work Group and Select Panel on Preconception Care, MORBIDITY & MORTALITY WEEKLY REPORT, (CDC, Atlanta, Ga.), April 21, 2006, at 1-23.

¹² WHO, *Make every mother and child count*, WORLD HEALTH REPORT (WHO, Geneva, Switz.) (2005), *available at* http://www.who.int/whr/2005/whr2005_en.pdf (last visited Sept. 17, 2010).

¹³ Eunice Kennedy Shriver Nat'l Inst. of Child Health & Human Development, *Care Before & During Pregnancy – Prenatal Care*, http://www.nichd.nih.gov/womenshealth/research/pregbirth/prenatal_care.cfm (last visited Sept. 15, 2010).

¹⁴ Office of Population Affairs, *Healthy People 2010: Objectives for Improving Health*, http://www.healthypeople.gov/document/html/volume1/09family.htm (last visited Sept. 15, 2010).

¹⁵ L. Gavin, et al., *Sexual & Reproductive Health of Persons Aged 10-24 Years – United States*, 2002-2007, (CDC, Atlanta, Ga.), http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5806a1.htm (last visited Sept. 15, 2010).

¹⁶ Office of Population Affairs, *supra* note 14.

¹⁷ S. Alford, *Adolescent Pregnancy & Protective Behaviors*, (Advocates for Youth, Washington, D.C.), http://www.advocatesforyouth.org/storage/advfy/documents/adolpreg.pdf (last visited Sept. 15, 2010).

indicative of future contraceptive use in subsequent relationships.¹⁹ Sexually active adolescents who are able to gain access to contraception may not only prevent immediate unintended pregnancy during their teenage years, but may also use contraception throughout their lifetime, helping substantially reduce the chances of having an unwanted or unintended pregnancy.

For adolescents, in particular, it is also important that access to contraception be accompanied with comprehensive sexual health education to ensure that contraception is used correctly. In a study of sexually active adolescents in 2003, it was reported that only twelve percent failed to use any method of contraception. Yet, even with a high rate of contraceptive use, 90 percent of unintended pregnancies resulted from inconsistent or incorrect use of contraception. It is also more likely that contraceptive devices be used less consistently when a person has an ambivalent attitude toward avoiding pregnancy. Providing sexual health education alongside contraceptive access for teens may substantially increase and improve the use contraception.

Contraception has been proven an effective method for reducing unwanted pregnancy. Publicly funded contraception has enabled low-income women and adolescents to prevent nearly two million unintended pregnancies each year in the United States. The Guttmacher Institute reports that without publicly funded contraceptive services, it is estimated that the rate of unintended pregnancy, birth and abortion "would be almost two-thirds higher among women overall and nearly twice as high among poor women." Similar to publicly-funded contraception, expanding Section 2713 to include contraception will help prevent unwanted pregnancy, and, in turn, reduce the likelihood of adverse medical consequences with pregnancy and birth.

Prenatal counseling decreases pregnancy and birth complications

The Interim Final Rules provide many prenatal care services; however, one preventive service that is not included is prenatal counseling. Prenatal counseling is one of the best ways to ensure healthy pregnancy and birth, as it allows a pregnant woman (or a woman seeking to become pregnant) to have access to ongoing medical care in her pregnancy. According to the National Institutes of Health, "[p]renatal healthcare is more than just healthcare; it often includes education and counseling about how to handle different aspects of pregnancy, such as nutrition and physical activity, what to expect from birth itself, and basic skills for caring for your infant."²⁴

Pregnant women who undergo prenatal counseling are able to have their pregnancies assessed on a regular basis for any complications. Such complications that could arise include fetal abnormalities and decline of fetal development and/or health. Catching these complications early in the pregnancy could reduce further complications to the pregnancy or the fetus, and could also help a pregnant woman choose which course of medical treatment is best for her well being.

Additionally, prenatal counseling provides pregnant women (or women who wish to become pregnant) who have existing medical problems ongoing assessments of the risks associated with pregnancy. For instance, obesity during pregnancy can lead to gestational hypertension, diabetes and Cesarean delivery, as well as increase the likelihood that the infant will be obese, have diabetes and be born with congenital heart defects.²⁵ For women with existing medical problems, early discussions with a physician about how

¹⁹ *Id*.

²⁰ Id.

²¹ Id.

²² Id.

²³ Sonfield, supra note 2.

²⁴ Eunice Kennedy Shriver Nat'l Inst. of Child Health & Human Development, supra note 13.

²⁵ Dr. J. Mills, Risk of Newborn Heart Defects Increases with Maternal Obesity, (Eunice Kennedy Shriver Nat'l Inst. of Child

pregnancy will impact their health increases patient education and awareness, early detection of problems and helps prevent further complications.

There is strong support for including well-woman visits as preventive care

A well-woman visit is a yearly health exam that includes a breast and pelvic exam and sometimes a pap smear. This visit is also an opportunity to discuss medical problems with a nurse or doctor and provides an excellent opportunity for early detection of serious medical problems.

Well-woman visits are considered preventive services by mainstream medical associations and are included in most preventive care guidelines. For instance, HHS noted that pap smears are a form of preventive care, and that "[c]ounseling, education, and screening can help prevent or minimize the effects of many serious health conditions." The CDC also reports that the pap test is a screening tool necessary for the early detection of cervical cancer. In addition, ACOG states that "[r]egular visits to the ob-gyn help ensure that you [women] receive age-appropriate screenings, exams, and immunizations and allow physicians to identify and treat common problems before they become a serious health risk." ACOG has additionally recommended that well-woman visits begin between the ages of 13-15 to increase efficacy of preventive health services. ²⁹

For many women, the well-woman visit is the only time they visit a medical professional. Due to the sensitivity of the information discussed during the visit, well-woman visits and exams provide an excellent point of medical intervention for more serious physical and mental health problems. Although the Interim Final Rules already provide for many services provided in well-woman exams, such as screenings for breast cancer, cervical cancer, chlamydia, gonorrhea and counseling for sexually transmitted infections, other health issues can also easily be detected during the visit. The well-woman visit is also an opportunity to identify and hopefully prevent intimate partner violence, rape/sexual assault, and other health conditions, such as endometriosis, depression, or hypertension. Since well-woman visits provide such a crucial point of intervention for women's health, expanding Section 2713(a)(4) to include well-woman visits is in line with the legislative intent to improve women's health services.

The Timeline for Implementing Women's Health Services Should Not be Unreasonably Delayed We also support an additional comment from our coalition partners of Raising Women's Voices for the Health Care We Need, of shortening the timeline for developing HRSA guidelines for women's health services so that these services are available soon after the broader requirements of Section 2713 are in effect. In particular, we support the recommendations that:

• The Institute of Medicine (IOM) adopt a two-step process, such that: 1) the IOM sends HRSA a list of services readily identified by accepted medical authorities as standards of care to be included in an interim guideline mandating coverage of, and prohibiting cost-sharing for, those services; and 2) that the IOM complete its review and develop recommendations for the remaining services not identified in the list to HRSA; and

Health & Human Development, Rockville, Md.), http://www.nichd.nih.gov/news/resources/links/ transcript040710.cfm (last visited Sept. 15, 2010).

²⁶ U.S. Dep't of Health & Human Services, http://mchb.hrsa.gov/whusa08/hsu/pages/304pc.html (last visited Sept. 15, 2010).

²⁷ CDC, http://www.cdc.gov/cancer/gynecologic/basic info/prevention.htm (last visited Sept. 15, 2010).

²⁸ Am. Coll. of Obstetricians & Gynecologists, *Practice Healthy Living in 2009*, http://www.acog.org/from_home/publications/press_releases/nr01-05-09.cfm (last visited Sept. 15, 2010).

²⁹ Am. Coll. of Obstetricians & Gynecologists, *Tool Kit for Teen Care* (2d ed. 2009), *available at* http://www.acog.org/departments/adolescentHealthCare/ TeenCareToolKit/SuggestedResponsesLT2.pdf (last visited Sept. 15, 2010).

• The timeline for insurers to comply with the guidelines be shortened to one month instead of the proposed one year. In light of the fact that the broader requirements of Section 2713 will already be in effect and that insurers will have already created a system of compliance for preventive health services, it is unnecessary that insurers be given an additional year to comply with the coverage requirements and cost-sharing prohibitions for women's health preventive services.

Section 2713 Should Apply to Medicaid and Medicaid Managed Care Programs, Including EPSDT Services for Youth

Medicaid currently covers one in six people, and it is the largest source of insurance for children in our nation. Even though the government may finance Medicaid managed care, the private plans organize and deliver the medical care. This means that although the Early and Periodic Screening, Diagnosis and Treatment (EPSDT) mandate requires coverage of all preventive care services, access to preventive coverage varies widely across programs. For instance, adolescents who receive EPSDT services may not be able to access contraception or comprehensive sexual health education. We therefore additionally recommend that Section 2713 apply to all Medicaid managed care contracts.

Expanding Section 2713 to managed care programs is also consistent with the legislative intent and statutory framework of PPACA because legislative history suggests using a national guideline in allowing states to set screening in consultation with child health experts. In addition, it is important to note that fee-for-service and managed care plans are already associated with the Bright Futures national health supervision guidelines in the CHIP regulations, 42 CFR 457.520(b). Expanding 2713 to managed care programs while still maintaining a tie to Bright Futures will help streamline administration and services and ensure that children receive the preventive services they need to live healthy lives.

PPACA §1557 Should be Incorporated and Applied to Preventive Services

Section 1557 of PPACA forbids discrimination on the grounds of sex, race, national origin, disability or age in health programs or activities receiving federal financial assistance or by programs administered by an Executive Agency or any entity established under Title I of PPACA. Since §1557 applies broadly to federally conducted programs and to entities that receive federal funding or assistance, it is essential that as federal agencies issue regulations for PPACA, they consistently incorporate the mandates of §1557. As the preventive services requirements are administered by an Executive Agency, we recommend that the Department clarify the application of §1557 to preventive services.

Incorporating the nondiscrimination requirements of §1557 will ensure that as our health care system reaches more Americans and makes coverage more affordable, it does so in a manner free from discrimination. Therefore, it is imperative that regulations implementing the law, including the final regulations regarding grandfathering status, incorporate §1557's mandate and make covered plans, providers and other programs aware of their obligation to comply with the nondiscrimination protections of the law.

Preventive Services Should be Delivered in a Culturally Sensitive and Linguistically Appropriate Manner

In recognition that our nation is made up of an increasingly diverse population, we strongly recommend that preventive services be provided in a culturally sensitive and linguistically appropriate manner. In particular, we strongly suggest the regulations clarify that a plan or issuer that provides preventive health services also provide and pay for any language services necessary to ensure effective communication with enrollees who have limited English proficiency (LEP). It is critical that language services, including oral interpretation and written translations, are provided to LEP enrollees so that they can understand the availability of preventive services and are fully informed of the preventive services that can be accessed.

According to the American Community Survey, over 55 million people speak a language other than English at home. Nearly 5% of all households are deemed "linguistically isolated," meaning that every member of the household over age 14 speaks English less than very well. Over 25 million (9% of the population) speak English less than "very well," and for health care purposes may be considered LEP.

Language access is one aspect of cultural competence that is essential to quality care for LEP populations. Health care providers from across the country have reported language difficulties and inadequate funding of language services to be major barriers to LEP individuals' access to health care and a serious threat to the quality of the care they receive. Research documents how the lack of language services creates a barrier to and diminishes the quality of health care for limited English proficient individuals. Language barriers impact access to care: non-English speaking patients are less likely to use primary and preventive care and public health services and are more likely to use emergency rooms, and once at the emergency room, they receive far fewer services than their English speaking counterparts.

Pursuant to PPACA §1557, and, to the extent that the plans or issuers receive federal financial assistance, to Title VI of the Civil Rights Act of 1964, plans and issuers are required to provide enrollees with language services. To ensure consistency for plans and issuers who have to comply with both PPACA §1557 and the HHS "LEP Guidance" (which outlines language access for federal fund recipients under Title VI), we believe that the OCIIO should, at a minimum, adopt the "LEP Guidance" and require that language services be provided to LEP individuals in conjunction with all preventive services. This would include oral communication for all individuals and, when certain thresholds are met, written translated materials. Regardless of whether translated materials are provided, the providers of preventive services

³⁰ L. Ku & A. Freilich, Kaiser Comm'n on Medicaid & the Uninsured, Caring for Immigrants: Health Care Safety Nets in Los Angeles, New York, Miami, and Houston, ii-iii (2001), available at http://aspe.hhs.gov/hsp/immigration/caring01/report.pdf (last visited Sept. 17, 2010); see also Inst. of Medicine, Unequal Treatment: Confronting Racial and Ethnic Disparities in Health, 71–72 (2002), available at http://download.nap.edu/cart/deliver.cgi?record_id=10260&type=pdf_chapter (describing recent survey finding 51% of providers believed patients did not adhere to treatment because of culture or language but 56% reported no cultural competency training).

³¹ See, e.g., G. Flores, et al., Errors in medical interpretation and their potential clinical consequences in pediatric encounters, 111 PEDIATRICS 6, 6-14 (2003), available at http://pediatrics.aappublications.org/cgi/content/full/111/1/6 (last visited Sept. 17, 2010); T.K. Ghandi, et al., Drug complications in outpatients, 15 J. OF GENERAL INTERNAL MEDICINE, 149, 149-154 (2000); Kathryn Pitkin Derose & David Baker, Limited English Proficiency and Latinos' Use of Physician Services, 57 MEDICAL CARE RESEARCH AND REVIEW, 76, 76-91 (2000); see also, Jacobs, et. al., Language Barriers in Health Care Settings: An Annotated Bibliography of the Research Literature (The California Endowment, Los Angeles, Cal.) (2003).

³² E.g. J. Bernstein, et al., Trained Medical Interpreters in the Emergency Department: Effects on Services, Subsequent Charges, and Follow-up, 4 J. OF IMMIGRANT HEALTH, 171, 171-76 (2002); I.S. Watt, et al., The health care experience and health behavior of the Chinese: a survey based in Hull, 15 J. Public Health Med. 129 (1993); S.A. Fox & J.A. Stein, The Effect of Physician-Patient Communication on Mammography Utilization by Different Ethnic Groups, 29 Med. Care 1065 (1991).

³³ *See* Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 Fed. Reg. 153, 47311, 47319-20 (Aug. 8, 2003), *available at* http://www.justice.gov/crt/cor/lep/hhsrevisedlepguidance.pdf.

³⁴ The relevant section from the HHS LEP guidance for written translation states: "Safe Harbor. The following actions will be considered strong evidence of compliance with the recipient's written-translation obligations:(a) The HHS recipient provides written translations of vital documents for each eligible LEP language group that constitutes five percent or 1,000, whichever is less, of the population of persons eligible to be served or likely to be affected or encountered. Translation of other documents, if needed, can be provided orally; or (b) If there are fewer than 50 persons in a language group that reaches the five percent trigger in (a), the recipient does not translate vital written materials but provides written notice in the primary language of the LEP language group of the right to receive competent oral interpretation of those written materials, free of cost. These safe harbor provisions apply to the translation of written documents only. They do not affect the requirement to provide meaningful access to LEP individuals through competent oral interpreters where an application of the four factor test leads to the determination that oral language services are needed and are reasonable. Conversely, oral

must ensure that LEP individuals understand the nature and scope of the services, any potential risks or side effects, required follow-up care and all other information that is provided to English-speaking patients.

Thank you for your consideration of our comments. If you should have any questions or need additional information, please do not hesitate to contact us at (202) 289-7661.

Sincerely,

/s/ Emily Spitzer Executive Director

interpretation of documents may not substitute for translation of vital written documents. For example, oral interpretation of the rules of a half-way house or residential treatment center may not substitute for translation of a short document containing the rules of the half-way house or residential treatment center and the consequences of violating those rules." *Id*.